Instructions for use
LGO-Bare Fiber Single Use

1. LGO-Bare Fiber Single Use

The LGO-Bare Fiber Single Use is an optical fiber for medical application in various fields of laser surgery. At the distal end of the LGO-Bare Fiber Single Use the cladding and coating of the optical fiber are removed on a length of 5 mm which ensures optimum energy transfer to the tissue that is to be treated. The proximal end the LGO-Bare Fiber Single Use is equipped with an SMA-905 connector or a custom special connector for connection to suitable medical laser devices. Prior to the treatment the compatibility must be checked.

1.1. Field of application and exceptions

The intended purpose of the LGO-Bare Fiber Single Use is to deliver laser energy from a source to the treatment site in laser surgery application.

The LGO-Bare Fiber Single Use is indicated in general laser surgery application of different disciplines such as incision, excision, vaporization and coagulation. With the LGO-Bare Fiber Single Use tissue can be cut out and the open resection surface can be simultaneously be sealed by the use of precise coagulation. Moreover, the product can be used for fragmentation of concrement (stones) or for creation of photo-chemical reactions.

Surgeries in the vicinity of brackets or implants are excluded because there is the risk of heating and destruction.

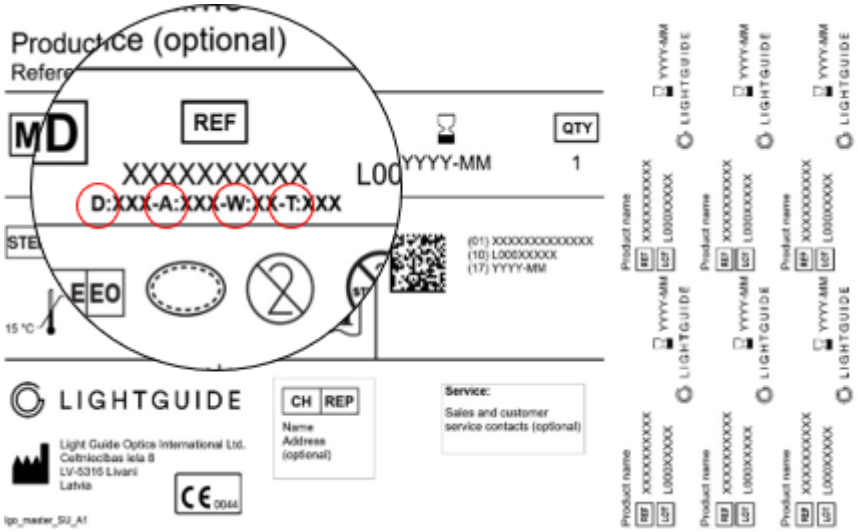
Follow current clinical guidelines. Applications at the central nervous system and the central circulatory system are not allowed. In order to ensure correct and save handling this device may only be applied by surgeons being familiar with the handling of medical laser devices, and with the therapeutic application of laser fiber probes.

1.2. Potential risks associated with the procedure

Please refer to the instructions for use of the medical laser device and the corresponding specialist medical literature for a full outline of possible side effects. Possible side effects can be but are not limited to: burns, swellings, bleeding, pain, infection, paraesthesia due to injury of adjacent sensory nerves, perforation in case of application in the vicinity of sensitive areas (artery, bowel, …). Moreover, unintended reactions of the treated tissue can be caused because of wrong (for example too high) laser settings.

1.3. Compatibility check

The compatibility of the LGO-Bare Fiber Single Use with the laser device must be checked. Information is provided on the device label. If the manufacturer of the laser device offers the LGO-Bare Fiber Single Use as a genuine accessory, the compatibility test with the laser device has already been performed and does not need to be performed again.



Compatibility code on the device label

D parameter - Beam diameter

The laser device in use must not have a beam diameter larger than the core diameter of the optical fiber. The core diameter of the optical fiber is given in units of microns.

A parameter - Numerical Aperture

The numerical aperture (NA) of the laser device in use must not exceed the value of parameter “A”.

W parameter - Wavelength

The wavelength range of the optical fiber is specified in the label:

- UV: 200 – 1000 nm;
- IR: 400 – 2200 nm.

T parameter - Type of connector

Verify that the port of laser device is compatible with the connector of the optical fiber probe. Mind the Instructions for Use of the laser device, which may specify further requirements on the optical fiber probe.

The connector type of the optical fiber is given in the label as parameter “T”. Examples are:

- SMA: SMA-905 connector (IEC 60874-2);
- SC: SC connector (IEC 61754-4);
- NC: A proprietary connector (matches only selected laser devices marked as such);
- CC: Customer connector (matches only selected laser devices).

Maximum Power

The maximum laser power setting for all product variations is 100 W unless there is a dedicated labelling on the product.

In the case of doubt, contact your technical service or supplier and dispense with the treatment until the problem has been solved fully.

2. Application guidelines and safety rules

Prior to the start of the laser treatment, all necessary instructions for use of the equipment employed must be read and fully understood. In the case of doubt, please contact your technical service or supplier and dispense with the treatment until the problem has been solved fully.

2.1. Application guidelines

It can be applicable to use the LGO-Bare Fiber Single Use in conjunction with a handpiece or endoscope. In this case it is important that the optical fiber can be inserted smoothly into the working channel and always protrudes from the instrument during the treatment. In particular with bended working channels prior to the treatment it is to be evaluated carefully if the probe can be inserted without friction.

The tissue to be treated should always be visible to see the aiming beam and to monitor the effect of the laser radiation. For application in contact surgery, guide the distal end of the fiber across the tissue surface without applying pressure. Lateral pressure is to be avoided. During the course of the treatment the distal end must be checked for tissue residues and damages. Tissue adhesion reduces the amount of laser power which is available for the treatment and causes the probe to heat up, which shortens its lifetime. Potential adhesion of tissue should be removed after cool down of the optical fiber probe without or with only little laser power by carful rubbing at tissue. Burnt-in tissue must be removed carefully with a sterile moist swab.

Laser pyrolysis products (gas, steam, particles, infection aerosols, …), which are created during the treatment, should be removed using a suction system above the treated area. Gas embolisms can arise from using flushing gas.

Typical treatment parameters and laser settings depend on the individual case. Please consult the specialist medical literature. Always start with low power and adjust the laser settings depending on the course of the treatment while observing the effects on the tissue.

2.2. Warnings ⚠

The use of medical devices may result in biological risk. Medical devices have to be used and disposed of in accordance with legal regulations and accepted practice.

Applications at the central nervous system and the central circulatory system are not allowed.

Surgeries in the vicinity of brackets or implants are not allowed because there is the risk of heating and destruction.

When using a handpiece or endoscope, make sure that the LGO-Bare Fiber Single Use can be inserted into the working channel smoothly and always protrudes from the instrument during the treatment.

The general instructions and information with regard to a safe handling with laser radiation have to be applied (including eye protection). Safety relevant information has to be extracted from the labelling of the laser devices and their reference manuals.

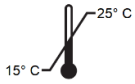
The handling of medical laser probes requires an enhanced care. Laser probes could be damaged by stresses, impacts or high-grade torsions. Such damages impact the functionality and/or appropriate operation/treatment. The LGO-Bare Fiber Single Use must never be bent too tightly during the procedure:

core diameter	**allowed bend radius**
≤ 400 µm	**≥ 21 mm**
≤ 600 µm	**≥ 31 mm**
≤ 1000 µm	**≥ 51 mm**

After connection to the laser device the aiming beam must be visible as a frontal emitting spot. If this is not the case the product must not be used.

After the treatment the LGO-Bare Fiber Single Use must be inspected for damages. In the unlikely event of the fiber tip breaking off and remaining in the body (or if this is considered possible) respective clinical measures are to be taken.

2.3. Symbol explanation

MD	Indicates the device is a medical device.
REF	Indicates the device's catalogue number.
	Manufacturer: Indicates the manufacturer of the medical device according to directive 93/42/EEC and regulation 2017/745/EU.
	Expiration date: Indicates the date after which the medical device must not be used.
LOT	Batch code: Indicates the manufacturer's batch code so that the batch or lot can be identified.
	The device must be stored in a dry place.
	The device must be stored at the given temperature range.
	Indicates a medical device that needs protection from light sources.
STERILE EO	The device has been sterilized with ethylene oxide (EO).
	Indicates a single sterile barrier system with protective packaging inside.
	Indicates a single sterile barrier system.
	Mind the instructions. It is necessary for the user to consult the instructions for use prior to use.
	Prior to use check the packaging for damage. The medical device should not be used if the packaging is damaged or unintentionally opened before use.
	Do not reuse. This device is intended for use with a single patient during a single treatment. Sterility and function cannot be guaranteed for reuse.
	Indicates a medical device that is not to be re-sterilized.
 (optional)	Indicates the entity distributing the medical device into the locale (Distributor).

3. Disclaimer

Light Guide Optics International Ltd is not liable for personal injuries as well as for damages of the laser device due to an inappropriate handling and storage of the LGO-Bare Fiber Single Use.

Light Guide Optics International Ltd cannot be held responsible for indirect damages or consequential damages, losses and expenses with respect to a direct or indirect application of these products.

Light Guide Optics International Ltd is not liable in terms of application of the LGO-Bare Fiber Single Use and in terms of possible side effects of the medical laser treatment with the laser fiber probes.

Light Guide Optics International Ltd.
Celtniecibas Street 8
LV-5316 Livani
Latvia
www.lightguide.com

Light Guide Optics Sales and Customer Service:
LightGuideOptics Germany GmbH
Tel. +49 2225 70953 0
Fax +49 2225 70953 20
E-Mail info@lightguide.de
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